AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
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WASHINGTON OFFICE

June 30, 2000

Lee D. Korb, Esq.
Docket Numbers 92N-0297 and 88N-0258
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20857

Dear Mr. Korb:

Thank you for providing an opportunity to comment on the final rule prohibiting blood centers functioning as "health care entities" to act as wholesale distributors of blood derivatives, as set forth in the Prescription Drug Marketing Act of 1987 and modified by the Prescription Drug Amendments of 1992 and the Food and Drug Administration Modernization Act of 1997.

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists (PhD), and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the world's leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

ASCP does not agree that full-service blood centers should be included under the definition of "health care entity." We request clarification regarding whether blood centers that do not provide diagnostic, medical, surgical or dental treatment, or chronic or rehabilitative care, but do provide products and services to individuals and institutions that meet the criteria of a health care entity, would be permitted to distribute blood derivative products under the rule.

The final rule may disrupt availability of blood derivatives to the public. As stated in the *Federal Register* notice, blood derivatives may be manufactured in large quantities and distributed by conventional drug wholesalers. However, some derivative manufacturers consider blood centers a local backup for their customers when the manufacturer is unable to fill an emergency order in a timely fashion. Additionally, small, regional hospitals requiring minimal, infrequent supplies rely on blood centers to support their needs since some manufacturers prefer not to service these hospitals. The supply of blood derivatives would be impeded if blood centers were prohibited from distributing these products.

Blood centers partner with local health departments to manufacture and distribute certain blood derivatives. If the final rule restricts such a partnership, the products will no longer be produced. Immune globulin and orphan biologics are manufactured and distributed under such a

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partnership. As one of the few sources nationwide for immune globulin, one particular blood center was called upon by the Centers for Disease Control and Prevention (CDC) to supply the product during an acute shortage a few years ago. Without their contribution, it would have been difficult for the CDC to manage the Hepatitis A outbreaks occurring at that time.

A blood center may partner with a health care entity, such as a local non-profit hemophilia center. The blood center may operate a restricted-service, on-site pharmacy that dispenses and delivers derivatives to the hemophilia center's patients for home infusion. Such an arrangement offers hemophilia patients an option for obtaining factor products at a reasonable cost. If the final rule goes into effect, such a pharmacy would no longer be permitted to operate.

Blood centers may also provide services such as typing and cross-matching of red cells for transfusion. This is especially helpful for smaller and rural hospitals and health care providers that cannot provide full transfusion-related medical services.

The regulation would have a negative economic impact on blood centers. Generally, they are not-for-profit entities, and there are only a small number of products and services that they can offer their customers. Each product and service is critical to maintaining a break-even status. Imposing restrictions on already limited operations could jeopardize their continued existence.

If you have questions or need additional information, please give me a call or contact Jennifer Burpee, MPH, ASCP Regulatory Associate, at (202) 347-4450.

Sincerely,

Stebbins Chandor, MD, FASCP
President

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